

REMARKS

These remarks are in response to the office action mailed May 2, 2008. Claim 1 has been amended. Support for the amendment can be found, for example, in claim 13 as filed. No new matter is believed to have been introduced.

I. REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 41 and 42 stand rejected as allegedly unclear regarding what dose/fluence is claimed. Applicants respectfully submit that claims 41 and 42 specifically recite in the alternative four (4) different dose/fluences. Applicants submit that the claim is clear and definite and respectfully request withdrawal of the rejection.

II. REJECTION UNDER 35 U.S.C. §103

Claims 1-8, 10-12, 14, 16-17, 24 and 41-42 are rejected under 35 U.S.C. §103 as allegedly unpatentable over Levy *et al.* (U.S. Patent No. 5,798,349) in view of Jampol *et al.* Applicants respectfully traverse this rejection.

The Applicants recognized that one can treat neovascularization of the eye by treating extrafoveal feeder vessels with doses of energy in excess of what one would use to treat the foveal or subfoveal areas of the eye. Furthermore, Applicants recognized the importance of treating and the advantages of treating feeder vessels in the extrafoveal areas.

The Applicants respectfully submit that even under the relaxed standards of *KSR v. Telflex*, the Office must still demonstrate each and every element of Applicants' claimed invention to provide a *prima facie* case of obviousness. Furthermore, when viewing the more unpredictable arts (e.g., biotechnology, medical therapies) the "teaching, suggestion and motivation (TSM)" test is appropriate. Unlike predictable arts having easily combined elements, the unpredictable arts lack the ease of combining elements with a predictable result. As described below the Office has failed to provide each and every element either in the references cited in the Final Office Action or in the knowledge available to one of skill in the art. Applicants will make the clear in the remarks below.

Levy *et al.* (the primary reference) do not teach or suggest (i) topical application of a photosensitizer, (ii) use of a high speed scanning laser ophthalmoscope, (iii) the use of indocyanine green, (iv) the use of non-coherent light, and/or targeting (e.g., identifying and exposing) choroidal neovascularization in the extrafoveal area, or (v) identifying a feeder vessel in an extrafoveal area. In the Advisory Action mailed September 24, 2008, the Examiner alleges that these remarks do not pertain to the claims being rejected, Applicants respectfully disagree. The primary reference is applied to claim 1, which includes the element of identifying feeder vessels in the extrafoveal area.

The specification describes the importance of identifying and treating a feeder vessel is important in stopping neovascularization in the extrafoveal area. Typically PDT treats neovascularization in the region of vessel growth within the foveal area (NOT the extrafoveal area). Furthermore, PDT used at the time of conception of the present invention was directed to the foveal area using doses below 50 J/cm² to prevent damage. Furthermore, PDT used at the time of conception of the present invention did not target feeder vessels in the extrafoveal area. Levy *et al.* do not teach or suggest these important considerations or elements.

To overcome these deficiencies the Office combines Jampol *et al.* with Levy for the alleged teaching of exposing the extrafoveal area to PDT. Jampol *et al.*, however, do not discuss or described identifying a feeder vessel in the extrafoveal area. As described in the present application the importance identifying a feeder layer is important in reducing further neovascularization. "The advantage to treating feeder vessels is the possibility that a large CNV complex can be eliminated by closing a small number of feeder vessels. Further, feeder vessels are generally localized to an area outside the central portion of the macula (i.e., the vessels are "extra-foveal")." (paragraph [0009] of publication no. 20060258629). Levy *et al.* in combination Jampol *et al.* fail to teach, suggest or contemplate these aspects. Only in hindsight is the importance of the claimed invention identified. The test for obviousness is not what one gleans from the teachings of the application during examination by the Office, but rather what, standing in the shoes of the inventor(s) at the time the invention was conceived would render the invention obvious. As described above, the references and the understanding in the art does not support

the piecing together of the invention as suggested by the Office using hindsight. Applicants' position is supported by one of the references cited in the Final Office Action namely the Sullivan reference. Thus, the combination of references does not teach and suggest all of the elements of Applicants' claimed invention. Accordingly, the reference cannot render the claimed invention obvious.

Claims 1-8, 10-12, 14, 16-17, 24, and 41-42 stand rejected under 35 U.S.C. §103 as allegedly unpatentably over Sullivan in view of Jampol *et al.* and further in view of Miller *et al.* Applicants respectfully traverse this rejection.

Sullivan does not teach or suggest (i) topical application of a photosensitizer, (ii) use of a high speed scanning laser ophthalmoscope, (iii) the use of indocyanine green, (iv) the use of non-coherent light, and/or (v) photodynamic therapy of a feeder vessel in an extrafoveal region or area. In addition, Sullivan does not teach or suggest photodynamic therapy using a dose that is about 4x the standard recognized dose of about 12 J/cm² (e.g., about 50 J/cm², as recited in Applicants' claims). As the Examiner admits, Sullivan does not teach the method for treating an aberrant choroidal neovascularization in an extrafoveal area of the eye or the fluence of the photoactivating light.

Furthermore, if the Examiner takes the teachings of the reference being cited as a whole, Sullivan *et al.* teach away from such higher doses indicating that "the benefits of laser treatment are limited because laser photocoagulation damages the viable neurosensory retina. . ." (see, e.g., page 398 of Sullivan *et al.*). Such neurosensory portions of the retina include the foveal area.

Thus, Sullivan does not teach each and every element of Applicants' claimed invention and in fact teaches away from the invention.

To overcome the deficiencies of Sullivan, the Office combines Jampol *et al.* However, as described above, Jampol *et al.* also fails to teach or suggest at least the same elements as Sullivan. Thus the combination of Sullivan and Jampol *et al.* do not cure the deficiencies of the obviousness rejection because both references fail to teach or suggest at least the same three elements of Applicants' claimed invention.

Jampol *et al.* do not discuss or described identifying a feeder vessel in the extrafoveal area. As described in the present application the importance identifying

a feeder layer is important in reducing further neovascularization. "The advantage to treating feeder vessels is the possibility that a large CNV complex can be eliminated by closing a small number of feeder vessels. Further, feeder vessels are generally localized to an area outside the central portion of the macula (i.e., the vessels are "extra-foveal")." (paragraph [0009] of publication no. 20060258629).

To further overcome the deficiencies of Sullivan and Jampol *et al.*, the Office further adds Miller *et al.* Miller *et al.* allegedly teaches porphyrin administration for neovascularization. Miller *et al.* do not teach foveal or extrafoveal treatment or feeder vessel treatment in the extrafoveal area. Accordingly, the combination of Sullivan, Jampol *et al.*, and Miller *et al.* if combined fail to teach or suggest all the elements of Applicants' claimed invention. A *prima facie* case of obviousness requires that all the elements of the claims being rejected must be taught by the references alone or in combination. Accordingly, the rejection should be withdrawn.

Claims 1-12, 14, 16-17, 24, and 41-42 stand rejected under 35 U.S.C. §103 as allegedly unpatentable over Levy *et al.*, in view of Jampol *et al.* and further in view of Levy *et al.* (U.S. Patent No. 4,920,143). Applicants respectfully traverse this rejection.

The rejection of claim 1-8, 10-12, 14, 16-17, 24 and 41-42 over Levy in view of Jampol *et al.* was addressed above. Levy *et al.* ('143) is combined for the alleged teaching of topical application of a photosensitizer. Applicants respectfully submit that the addition of Levy *et al.* ('143) does not remedy the deficiencies of the combination of references found as applied to the previous claims (i.e., the independent claims). Thus, even *if* Levy *et al.* ('143) teach what the Examiner purports, the combination still fails to teach or suggest treating feeder vessels in the extrafoveal area.

The same can be said for the combination of Levy *et al.*, Jampol *et al.*, Miller *et al.* and Levy *et al.* ('143). Accordingly the rejection may properly be withdrawn.

Claims 1-8, 10-17, 24, and 41-42 stand rejected under 35 U.S.C §103 as allegedly unpatentable in view of Levy *et al.*, in view of Jampol *et al.*, and further in view of Roach (Eye Net Magazine March 2001). Roach is applied for the alleged

teaching of a digital imaging system for high-speed indocyanine green angiography coupled with a scanning laser ophthalmoscope. Even if there is some suggestion to combine Roach with the other references, which there is not, the result fails to satisfy the deficiencies of the independent claims as describe above. Roach does not teach or suggest all of the elements of Applicants' claimed invention, e.g., treating feeder vessels in the extrafoveal area with doses higher than the typical dose used in the foveal area.

Claims 1-8, 10-17, 24, and 41-42 stand rejected under 35 U.S.C §103 as allegedly unpatentable in view of Levy *et al.*, in view of Jampol *et al.*, and further in view of Miller *et al.*, and further in view of Roach (Eye Net Magazine March 2001). Applicants respectfully traverse this rejection.

The combination of Levy *et al.*, Jampol *et al.* and Miller *et al.* were addressed above. The combination of Levy *et al.*, Jampol *et al.* and Roach were addressed above. This further sub-combination does not address the deficiencies of the previous combinations in any order as they may be applied for the reasons set forth above. In particular, the combination fails to teach, suggest or appreciate treating feeder vessels in the extrafoveal space, among other deficiencies.

Claims 1-8, 10-18, 24, and 41-42 stand rejected under 35 U.S.C §103 as allegedly unpatentable in view of Levy *et al.*, in view of Jampol *et al.*, and further in view of LumaCare. Applicants respectfully traverse this rejection.

The combination of Levy *et al.*, Jampol *et al.* were addressed above. The Office attempts to overcome the deficiencies of the foregoing reference as it relates to non-coherent light of claim 18 by citing LumaCare. This further sub-combination does not address the deficiencies of the previous combinations in any order as they may be applied for the reasons set forth above. In particular, the combination fails to teach, suggest or appreciate treating feeder vessels in the extrafoveal space, among other deficiencies.

Claims 1-8, 10-18, 24, and 41-42 stand rejected under 35 U.S.C §103 as allegedly unpatentable in view of Levy *et al.*, in view of Jampol *et al.*, and further in

view of Miller *et al.*, and further in view of LumaCare. Applicants respectfully traverse this rejection.

The combination of Levy *et al.*, Jampol *et al.* and Miller *et al.* were addressed above. The combination of Levy *et al.*, Jampol *et al.* and LumaCare were addressed above. This further sub-combination does not address the deficiencies of the previous combinations in any order as they may be applied for the reasons set forth above. In particular, the combination fails to teach, suggest or appreciate treating feeder vessels in the extrafoveal space, among other deficiencies.

Respectfully, the Examiner appears to attempt to fill in any and all gaps with a general statement, "A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the might reasonably infer from the teachings." The Examiner appears to be attempting to infer upon an inference of a combination; this cannot be done. Applicants respectfully submit that the statement that the Examiner appears to be relying upon is related to "direct anticipation" and an inference of the references. This is different than an inference under an obviousness rejection. The rejections pending are not "direct anticipation", but are rather an inference of an inference.

For at least the foregoing, the Applicant submits that the claimed invention is patentable and request reconsideration and notice of such allowable subject matter.

The Director is authorized to charge any required fee or credit any overpayment to Deposit Account Number 50-4586, please reference the attorney docket number above.

The Examiner is invited to contact the undersigned at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

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